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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,226	11/01/2006	Alastair Edwin McAuley	FPHCR.104NP	7568

20995 7590 09/29/2011

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EXAMINER	
STUART, COLIN W	

ART UNIT	PAPER NUMBER
3771	

NOTIFICATION DATE	DELIVERY MODE
09/29/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/570,226	MCAULEY ET AL.	
	Examiner	Art Unit	
	COLIN W. STUART	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1,3,4,6,8-12 and 18-28* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,3,4,6,8-12 and 18-28* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *28 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to the request for continued examination and the amendments filed 8/1/11. As directed by the amendments claims 1, 10, and 12 have been amended, claims 26-28 have been added, and no claims have been cancelled. As such, claims 1, 3, 4, 6, 8-12, and 18-28 are pending in the instant application.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the fourth paragraph of 35 U.S.C. 112:

> Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

Claim 11 is rejected under 35 USC 112 4th paragraph, as it does not further limit the claim to which it depends on, claim 10. Claim 10 already includes the limitation that the outlet member is removable (see claim 10 line 7).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 3, 4, 6, 8-12, and 18-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gunaratnam et al. (7,066,178) in view of Walker et al. (7,089,939) and Wandel et al. (4,974,586).

In regards to claim 1, Gunaratnam shows a device for a supply of gases to a user which includes a mask 100, in use in fluid communication with a supply of gases and supplying the gases to a user (see Fig. 8 and col. 1 ln. 13-17 and col. 3 ln. 1-3), at least one outlet member in the form of a cover 114 integrated with or attached to the mask (see Fig. 8), wherein a boundary between the outlet member and the mask forms at least one outlet vent (at 110 Fig. 8) that in use passes a substantial portion of expired gases of the user (see col. 7 ln. 45-48), wherein the outlet vent includes a slot formed in the mask (116 see Fig. 8) and a cover 114 extending over the slot and attached to the mask for diffusing the exhaled gases (see col. 7 ln. 45-48). Gunaratnam is silent as to a separation between the mask and the cover increases at a location between the slot and an edge of the cover where the gases exit the outlet vent. However, Walker teaches a similar device which includes a cover and a mask forming an outlet vent wherein a separation between the mask and the cover increases at a location between

the slot and an edge of the cover where the gases exit the outlet vent (see Walker 138 Fig. 8). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Gunaratnam device's cover to extend such that a separation between the mask and the cover increases at a location between the slot and an edge of the cover where the gases exit the outlet vent as taught by Walker in order to increase the cross-sectional size of the outlet vent to decrease risk of occlusion. The modified Gunaratnam device is silent as to the vent passing expired gas in an upward direction toward the top of the user's head; however, the direction of the venting of the expired gas would have been considered to be an obvious design choice to one of ordinary skill in the art at the time the invention was made. Furthermore, Wandel teaches an outlet vent for expired air which vents the expired air in an upward direction toward the top of the user's head (see Wandel col. 6 ln. 23-26). It would have been obvious to modify the modified Gunaratnam device's outlet vent to vent expired air in an upward direction toward the top of the user's head, as taught by Wandel, in order to vent the air in "any desired direction" (see Wandel col. 6 ln. 25-26).

In regards to claim 3, the modified Gunaratnam device's outlet member is removable (see Gunaratnam col. 7 ln. 36-37).

In regards to claim 4, the modified Gunaratnam device's at least one outlet vent is a substantially long tapered slot (see Gunaratnam Fig. 8 and Walker Fig. 8).

In regards to claim 6, the modified Gunaratnam device's at least one outlet vent extends between the top and bottom of the mask (see Gunaratnam Fig. 8).

In regards to claim 8 and 9, the modified Gunaratnam device discloses that the mask is a nasal mask or a full face mask (see Gunaratnam col. 5 ln. 15-19).

In regards to claim 10, Gunaratnam shows a CPAP system for delivering gases to a user (see 1 ln. 13-17) which includes a pressurized source of gases (col. 3 ln. 1-3), a gas conduit in fluid communication with the pressurized source and a mask adapted to convey gases (see Fig. 8, tubing), and at least one removable outlet member in the form of a cover (114 see col. 7 ln. 36-37) integrated with or attached to the mask, wherein a boundary between the outlet member and the mask forms at least one narrow outlet vent that in use passes a substantial portion of expired gases of the user (col. 7 ln. 45-48), a slot formed in the mask (116) which the cover extends over to diffuse the exhaled gases. Gunaratnam is silent as to a separation between the mask and the cover increases at a location between the slot and an edge of the cover where the gases exit the outlet vent. However, Walker teaches a similar device which includes a cover and a mask forming an outlet vent wherein a separation between the mask and the cover increases at a location between the slot and an edge of the cover where the gases exit the outlet vent (see Walker 138 Fig. 8). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Gunaratnam device's cover to extend such that a separation between the mask and the cover increases at a location between the slot and an edge of the cover where the gases exit the outlet vent as taught by Walker in order to increase the cross-sectional size of the outlet vent to decrease risk of occlusion. The modified Gunaratnam device is silent as to the vent passing expired gas in an upward direction toward the top of the user's head;

however, the direction of the venting of the expired gas would have been considered to be an obvious design choice to one of ordinary skill in the art at the time the invention was made. Furthermore, Wandel teaches an outlet vent for expired air which vents the expired air in an upward direction toward the top of the user's head (see Wandel col. 6 ln. 23-26). It would have been obvious to modify the modified Gunaratnam device's outlet vent to vent expired air in an upward direction toward the top of the user's head, as taught by Wandel, in order to vent the air in "any desired direction" (see Wandel col. 6 ln. 25-26).

In regards to claim 11, the modified Gunaratnam device's outlet member is removable (Gunaratnam col. 7 ln. 36-37).

In regards to claim 12, Gunaratnam, Fig. 8, shows a removable outlet member (114 col. 7 ln. 36-37) for a gases delivery mask 100, in which the mask includes a slot 116 to which the outlet member, in the form of a cover 114, is provided on, and a boundary between the outlet member/cover and the mask forms at least one outlet vent 110 that in use passes a substantial portion of expired gases from a user (col. 7 ln. 45-48). Gunaratnam is silent as to a separation between the mask and the cover increases at a location between the slot and an edge of the cover where the gases exit the outlet vent. However, Walker teaches a similar device which includes a cover and a mask forming an outlet vent wherein a separation between the mask and the cover increases at a location between the slot and an edge of the cover where the gases exit the outlet vent (see Walker 138 Fig. 8). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Gunaratnam device's cover to

extend such that a separation between the mask and the cover increases at a location between the slot and an edge of the cover where the gases exit the outlet vent as taught by Walker in order to increase the cross-sectional size of the outlet vent to decrease risk of occlusion. The modified Gunaratnam device is silent as to the vent passing expired gas in an upward direction toward the top of the user's head; however, the direction of the venting of the expired gas would have been considered to be an obvious design choice to one of ordinary skill in the art at the time the invention was made. Furthermore, Wandel teaches an outlet vent for expired air which vents the expired air in an upward direction toward the top of the user's head (see Wandel col. 6 ln. 23-26). It would have been obvious to modify the modified Gunaratnam device's outlet vent to vent expired air in an upward direction toward the top of the user's head, as taught by Wandel, in order to vent the air in "any desired direction" (see Wandel col. 6 ln. 25-26).

In regards to claims 18, 22, and 24, the modified Gunaratnam device's separation between the mask and the cover increases to the edge of the cover (see Gunaratnam Fig. 8 and Walker Fig. 8).

In regards to claim 19, the modified Gunaratnam device's cover (Gunaratnam 114) includes a proximal end and a distal end, the proximal end located closer to the slot than the distal end (see Gunaratnam Fig. 8), wherein the separation between the mask and the cover increases from the proximal end to the distal end (see Gunaratnam Fig. 8 and Walker Fig. 8).

In regards to claims 20, 23, and 25, the modified Gunaratnam device appears to have an angle defined by the separation between the mask and the cover of between about 1 degree to about 20 degrees (see Fig. 8 of Walker). However, one of ordinary skill in the art at the time the invention was made would have found the angle as claimed to be an obvious matter of design choice; and furthermore one would expect the modified Gunaratnam device to perform equally as well with the claimed angle being between about 1 and 20 degrees.

In regards to claim 21, the modified Gunaratnam device includes a cross-sectional area between the mask and the cover which increases at a location between the slot and the edge of the cover along a direction towards the edge of the cover (see Gunaratnam Fig. 8 and Walker Fig. 8).

5. Claims 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gunaratnam et al. (7,066,178), Walker et al. (7,089,939) and Wandel et al. (4,974,586) as applied to claims 1, 10, or 12 above, and further in view of Japuntich et al. (6,460,539).

In regards to claims 26-28, the modified Gunaratnam teaches all the limitations as discussed above, but is silent as to the outlet member having a bottom edge that is shorter than its top edge. However, Japuntich teaches an outlet member of a vent for a respiratory mask which includes two edges in which one is shorter than the other (see Japuntich Fig. 4). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Gunaratnam device to include the

geometric shape of the vent as taught by Japuntich in order to provide an exhaust edge of the outlet member with a larger edge such that exhausted gas may disperse to the atmosphere and avoid jetting. Note that although Japuntich's vent bottom edge is larger, the geometric shape taught by Japuntich as applied to the modified Gunaratnam device is such that it gives a bottom edge with a shorter length than a top edge. Japuntich's outlet member exhaust edge length is greater than its edge which is connected to the mask (see Japuntich Fig. 4). With the above discussed modification, the modified Gunaratnam's outlet member includes a first edge near the slot and a second edge near a location where gases exit the outlet vent, wherein the width of the cover is greater at the second edge than at the first edge (claim 28) and the outlet member/cover includes a width that increases from its bottom edge to its top edge (claim 27).

Response to Arguments

6. Applicant's arguments with respect to claims 1, 3, 4, 6, 8-12, and 18-28 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Serowski (6,584,977) teaches an outlet member for a gases delivery mask which directs the exhausted air in an upward direction toward the top of the user's head.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to COLIN W. STUART whose telephone number is (571)270-7490. The examiner can normally be reached on M-Thr 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/COLIN W STUART/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771